Frequently Requested Information – Salt Lake

Toll-free: 800.826.2088 ServiceCenter@NelsonLabs.com
Local: 801-290-7500 Accounting@NelsonLabs.com
Fax: 801-290-7998 Sales@NelsonLabs.com

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Company Information	Nelson Laboratories, LLC (NL) a Sotera Health company, is an industry-leading provider of laboratory testing and consulting services. We perform over 400 rigorous microbiological and analytical laboratory tests across the medical device, pharmaceutical, and tissue industries. We know that every test matters and requires solutions to complex problems to improve patient outcomes and minimize client risk. A full description of services offered can be found on our website at www.nelsonlabs.com.		
	Established	1985	
Facilities	NL is located in Salt Lake City, Utah. There are five buildings (totaling 128,400 ft²) that comprise the NL campus: Redwood 1 and 2, Redwood 3, Redwood 4, and Redwood 5. The total combined laboratory space of the five buildings is 85,245 ft².		
	The state-of-the-art facilities are clean, organized, and secured with keycard and PIN access. Some key features include a multi-media auditorium, several large conference rooms, a metrology lab, a training lab, a media prep lab, five ISO Class 5 clean rooms, a cafeteria where lunch is catered daily, a children's playroom, and a registered art gallery.		
Audit Availability	An on-site audit may be arranged by contacting QualityAudits@nelsonlabs.com.		
References	NL policies and procedures ensure the protection of our clients' names, confidential, and proprietary information, thus no references are able to be provided.		
Critical Contacts	Joe Shrawder	President	Please contact our client services group at 801-290-7500 to arrange to speak with any of these individuals.
	Jeff Nelson	Chairman	
	John Bolinder	VP of Operations, North America	
	Todd Sierer	VP of Sales & Marketing	
	Rob Thoreson	Director of Quality Assurance	

Ownership	A Sotera Health company				**Federal Tax ID**	87-0425936		
Business Classification	NL does not meet the criteria for small business classification in 13 CFR Part 121. Sector 54 Professional, Scientific & Technical Services/NAICS 541380: Testing Laboratories.							
Dun & Bradstreet Number	15-166-3234							
Shifts	Primarily one shift, 9am-5pm, 5 days a week. Weekends and swing shifts as required.							
Payment Options	**Cash**	U.S. Funds	**Check**	Drawn on U.S. bank in U.S. dollars	**Credit**	Visa, MasterCard, American Express	**Net Terms**	30 days
Shipping Address	Attn: Log In or Receiving, 6280 South Redwood Road, Salt Lake City, UT 84123-6600 USA			**Billing / Payment Address (Check Remittance)**		Nelson Laboratories, LLC 29471 Network Place Chicago, IL 60673-1294		

ISO Accreditation	ISO Standard: ISO 17025 ISO Registrar: ANAB	Certificate Number: AT-1382 Please see up-to-date certificates on our website.	
FDA CDRH Registration	#1721109	**FDA FEI Identifier**	# 3000233845
FDA Audit Information	We are frequently audited by the FDA to GMP, GLP, and GTP guidelines. Please see up-to-date EIRs and responses on our website.		
EU GMP Certification	Certificate No: DK H 00083416 (DMA)		
Other Certifications	NL also holds certifications from the U.S. EPA, U.S. DEA, and U.S. OSHA		
US SAM Entity/DUNS/CAGE Code	NELSON LABS, LLC / 151663234 / 5ESY1		

Please note: This document is for informational purposes only and can change at any time.

Change Control and Change Notification	Since most of our testing services are based on standard testing procedures (STP), we provide the ability to have an additional "Customer Specification Sheet (CSS) or testing instruction" which provides customer specific instructions for testing (if necessary). The Customer Specification Sheet or testing instructions are reviewed and approved by the NL Study Director and if requested by your company prior to implementation. Additionally, all changes made through our change control process are assessed for the potential impact to you as a customer. We make every effort to contact our customers where appropriate. You may refer to our secure client website at www.nelsonlabs.com, for a posting of our most recent customer-applicable changes, as well as a list of all procedural updates.
Calibration and Maintenance	The calibration and maintenance of equipment is primarily performed by NL's Metrology Department. Using documented procedures, they work to prevent inaccuracy and deficiencies in data through the use of NIST traceable reference standards, laboratory working standards, and tests for use in calibration.
Complaints	NL has a formalized complaint resolution process and seeks customer feedback on a regular basis.
Control of Non-conforming Product	Items which do not conform to purchase order specifications are quarantined.
Corrective Action / Preventative Action	A Corrective Action/Preventive Action (CAPA) procedure is in place to address potentially recurring quality problems. The procedure includes root cause analysis, verifying and validating corrective and preventive action, implementing and recording changes in applicable procedures, ensuring that the appropriate people are aware and involved in the preventive actions, and effectiveness verification. All CAPA action plans are reviewed and approved by management.
Design Control	Design review is required for most new Standard Test Protocols. Test methods adapted from a compendial standard are exempt.
Deviations	Our Quality Events and Investigations procedure details how to address a deviation, a specific change to a procedure that does not impact safety or efficacy, and complies with the provisions of ISO 17025, EPA and FDA regulations. This procedure requires that all deviations be documented, assessed for impact, where appropriate investigated, and properly reviewed and authorized before the release of data. If a deviation impacts a sponsor's test or data, the sponsor is contacted within one business day. Approved deviations are documented in the final report.
Document Control	NL establishes and maintains procedures to control all documents required by regulations, standards, normative documents, test, and calibration methods. Documents are controlled by revision number electronically through MasterControl, our document control software. Documents are reviewed, updated, and approved as necessary.
Equipment	Each piece of equipment is uniquely identified. Before being put into use, a new piece of equipment undergoes IQ, OQ, and PQ.
Internal Audits	NL has a formal, documented internal audit program. Each applicable ISO 17025, GMP, GLP, and GTP clause as well as each NL laboratory section is audited at least once on an annual schedule. Actions to correct deficiencies and prevent recurrence are documented, reviewed, and approved before audit closure.
Management Responsibilities	NL Management has established a Quality Policy and organizational structure. Management reviews the effectiveness of the NL Quality System on a bi-annual basis according to ISO/IEC 17025:2005 and 21 CFR part 820.40.
Out of Specification (OOS) Results	An OOS is a result that falls outside the specification established by a compendial method, SOP, STP, Protocol, or as required by the sponsor. According to the Quality Events and Investigations procedure, an OOS must be documented, root cause identified through a failure investigation, its impact to data assessed and the validity of any results substantiated. If an OOS impacts a sponsor's test or data, the sponsor is contacted within one business day.

Purchasing Controls	Supplies are received at the warehouse receiving station and initially inspected. Receiving staff verify the purchase order against the packing slip and other receiving documents. Also verified are quantity, product identification and container integrity. Any discrepant items are quarantined until disposition. Items with further inspection and/or testing requirements are transferred to a designated Quality Control (QC) quarantine processing area until required acceptance testing is completed. As with receiving, any discrepant items are quarantined until disposition. Disposition is documented.
Quality Manual/Policy	The NL Quality Manual provides the employees, auditors, and customers of Nelson Labs with a description of the Quality Management System and Quality Policy. It is organized according to the format of ISO 17025 to facilitate audits of NL systems to the requirements of these standards.
Statistical Techniques	Statistical controls are applied as required by test methods. Any statistical techniques applied to analyze data are described in the final test report. We utilize validated spreadsheets to perform calculation and have uncertainty data calculated for test methods where applicable.
Study Documentation	Datapacks, which contain study information including raw data, are scanned and maintained. NL's Quality Document retention period is 10 years.
Supplier Management	All suppliers are qualified through our supplier management process. The quality capabilities of vendors/subcontractors are reviewed prior to placing any orders. Supplier performance is assessed on an ongoing basis through product quality tracking systems.
Test Data Review	All raw test data undergoes, at a minimum, a full review by a Study Director. Many studies receive an additional review by a Technical Reviewer or a member of Quality Assurance. For GLP studies, this review is performed by trained Quality Assurance inspectors.
Traceability	Process controls are in place to ensure traceability and to prevent contamination. Samples are coded with a bar code sticker. Associated items used in testing are traceable to the batch record, lot number, or part number.
Training	NL includes an onsite professional development department and an extensive, documented training program for all employees. All employees receive annual GMP, GLP, and GTP training. Additionally, annual proficiency and competency analyses are performed (where applicable).
Validation	Analytical test methods undergo validation to assess accuracy, precision, specificity, detection limit, quantitation limit, range and linearity, (where applicable).